

Application No. PG3614USW
Attorney Docket No. 09/914,830

In the Claims:

1. (Currently Amended) A portable, hand-held, patient-operable device for the delivery of inhalable medicament comprising:

(a) a housing adapted to be carried by a patient breathing without the assistance of a respirator and sized to fit within the patient's hand while said device is in use by the patient;

(b) a monitor for monitoring the breath cycle of a patient positioned within said housing;

(c) a medicament container having a release mechanism releasing inhalable medicament therefrom; and

(d) an actuator for actuating said release mechanism, said actuator being actuatable in response to a signal from said monitor,

characterized in that the monitor provides said signal at a trigger point which is correlated to the end of the exhalation part of the breath cycle.

2. (Original) A portable device according to claim 1, wherein said monitor comprises one or more sensors for sensing the pressure profile associated with the breath cycle.

3. (Previously presented) A portable device according to claim 1, wherein said monitor comprises one or more sensors for sensing the airflow profile associated with the breath cycle.

4. (Previously presented) A portable device according to claim 1, wherein said monitor comprises one or more sensors for sensing the temperature profile associated with the breath cycle.

Application No. PG3614USW
Attorney Docket No. 09/914,830

5. (Previously presented) A portable device according to claim 1, wherein said monitor comprises one or more sensors for sensing the moisture profile associated with the breath cycle.
6. (Previously presented) A portable device according to claim 1, wherein said monitor comprises one or more sensors for sensing the oxygen or carbon dioxide profile associated with the breath cycle.
7. (Previously presented) A portable device according to claim 1, wherein the trigger point corresponds to the point at which the lungs of the patient are most empty.
8. (Previously presented) A portable device according to claim 1, wherein said monitor is connectable to an electronic information processor.
9. (Original) A portable device according to claim 8, wherein said electronic information processor includes an active memory for storing information about the breath cycle.
10. (Original) A portable device according to claim 9, wherein said electronic information processor includes a predictive algorithm for predicting the optimum trigger point.
11. (Original) A portable device according to claim 9, wherein said electronic information processor includes a look-up table for predicting the optimum trigger point.
12. (Previously presented) A portable device according to claim 9, wherein said electronic information processor includes a second predictive algorithm for predicting the optimum amount of medicament to release.

Application No. PG3614USW
Attorney Docket No. 09/914,830

13. (Previously presented) A portable device according to claim 9, wherein said electronic information processor includes a second look-up table for predicting the optimum amount of medicament to release.
14. (Previously presented) A portable device according to claim 12, wherein said electronic information processor includes a dose memory for storing information about earlier delivered doses and reference is made to the dose memory in predicting the optimum amount of medicament to release.
15. (Previously presented) A portable device according to claim 12, additionally comprising a display for displaying information about the optimum amount of medicament to release.
16. (Previously presented) A portable device according to claim 12, additionally comprising a selector for selecting the amount of medicament to release.
17. (Original) A portable device according to claim 16, wherein the selector is manually operable.
18. (Original) A portable device according to claim 16, wherein the selector is operable in response to a signal from the electronic information processor.
19. (Previously presented) A portable device according to claim 16, wherein the selector comprises a timing mechanism for varying the time interval of actuation of the actuator.
20. (Previously presented) A portable device according to claim 16, wherein the selector comprises a metering mechanism between the container and the release mechanism for metering a variable quantity of medicament for release.

Application No. PG3614USW
Attorney Docket No. 09/914,830

21. (Previously presented) A portable device according to claim 16, wherein the selector comprises a multiple-fire mechanism for multiple actuation of the actuator, wherein each actuation releases a portion of the optimum amount of medicament.
22. (Currently amended) A portable device according to claim 1, wherein said medicament container is an aerosol container containing a medicament formulated in a pressurized liquid propellant and said release mechanism is an aerosol valve.
23. (Original) A portable device according to claim 22, wherein said aerosol valve includes a metering chamber for metering the release of medicament.
24. (Original) A portable device according to claim 23, wherein the metering chamber has a variable metering volume.
25. (Original) A portable device according to claim 24, wherein the metering chamber comprises a chamber of fixed volume which metering volume is variable by insertion of a plunger or piston.
26. (Original) A portable device according to claim 24, wherein the metering chamber is formed from an expandable material.
27. (Original) A portable device according to claim 24, wherein the metering chamber has a telescopic or concertina arrangement.
28. (Previously presented) A portable device according to claim 1, wherein said medicament container is a dry-powder container or a liquid container.
29. (Previously presented) A portable device according to claim 1, wherein said actuator comprises an energy store for storing energy which energy is releasable to activate the release mechanism of the medicament container.

Application No. PG3614USW
Attorney Docket No. 09/914,830

30. (Original) A portable device according to claim 29, wherein said energy store comprises a biasable resilient member.
31. (Original) A portable device according to claim 30, wherein said biasable resilient member is a spring.
32. (Original) A portable device according to claim 29, wherein said energy store comprises a source of compressed fluid, preferably compressed gas.
33. (Original) A portable device according to claim 29, wherein said energy store comprises a voltaic cell or battery of voltaic cells.
34. (Original) A portable device according to claim 29, wherein said energy store comprises a chemical energy source, preferably a chemical propellant or ignition mixture.
35. (Original) A portable device according to claim 29, wherein said energy store comprises a physically explosive energy source.
36. (Previously presented) A portable device according to claim 1, additionally comprising a safety mechanism to prevent unintended multiple actuations of the actuator.
37. (Original) A portable device according to claim 36, wherein said safety mechanism imposes a time delay between successive actuations of the actuator.
38. (Previously presented) A portable device according to claim 1, additionally comprising an actuation counter.
39. (Previously presented) A portable device according to claim 1, additionally comprising a medicament release counter, preferably a dose counter.

Application No. PG3614USW
Attorney Docket No. 09/914,830

40. (Previously presented) A portable device according to claim 1, additionally comprising a manual override.

41. (Previously presented) An inhalation device for the delivery of inhalable medicament comprising a housing and a system according to claim 1.

42. (Currently amended) A method for the delivery of inhalable medicament to a patient by way of a portable, handheld, patient-operable device comprising

- (i) monitoring the breath cycle of a patient by use of a monitor;
- (ii) at a trigger point, sending an actuation signal from said monitor to an actuator;
- (iii) on receipt of said actuation signal by said actuator, actuating the release of inhalable medicament to the patient,

characterized in that said trigger point is ~~coupled~~ correlated to the end of the exhalation part of the breath cycle.

43. (Original) Method according to claim 42, wherein steps (i) to (iii) are repeated until the breath cycle corresponds to a medically acceptable form.

44. (Original) Method according to claim 42, comprising

- (i) monitoring a plurality of breath cycles of a patient by use of a monitor;
- (ii) analysing said plurality of breath cycles to define an averaged breath cycle for the patient;
- (iii) predicting a trigger point from said averaged breath cycle, the trigger point being coupled to the end of the exhalation part of the averaged breath cycle;

Application No. PG3614USW
Attorney Docket No. 09/914,830

(iv) monitoring a further breath cycle and at said predicted trigger point sending an actuation signal from said monitor to an actuator;

(v) on receipt of said actuation signal by said actuator, actuating the release of inhalable medicament to the patient.